EXHIBIT 4

December 15, 2017

Expert Report of William W. Fox, MD and Thomas H. Shaffer, MS.E., Ph.D.

I. INTRODUCTION

We have been retained by Richard K. Hines ("Hines") to provide our expert opinion regarding the legal case involving "Goodrich V. Fisher-Price, Inc." ("Case"). In this regard, we have been asked by "Hines" to provide this expert report to explain our opinions in the Case.

II. PROFESSIONAL BACKGROUND

A. *Dr. Fox Academic Profile*

1. I have worked in the field of pediatrics, neonatology, respiratory physiology and prevention of injury related to suffocation/ strangulation in infants and children for over 45 years. My curriculum vitae is provided in **Appendix A**.

2. I currently serve in multiple capacities as Professor of Pediatrics, Department of Pediatrics, The Children's Hospital of Philadelphia, and University of Pennsylvania School of Medicine.

3. I served as Medical Director, Infant Intensive Care Unit, The Children's Hospital of Philadelphia, Philadelphia, PA during 1978-94.

4. Since 1978, I have served as Director, Infant Breathing Disorder Center, The Children's Hospital of Philadelphia, Philadelphia, PA

5. I received my B.S. from Duke University, Durham, NC in 1962 and my M.D. from Duke University Medical School, Durham, NC in 1966.

6. As my military service, 1967-69, I taught in two Bolivia Medical Schools, was Co-Director of a huge Tuberculosis Control Program with the Peace Corps; U.S. Public Health

Service, Bolivia, South America. Throughout my professional career, I go back yearly to Bolivia to lecture in Spanish on advances in neonatology and pediatrics.

7. I have been a Professor of Pediatrics for almost 30 years. Children's Hospital has been ranked as Number one or two in the US for at least 10 years. The Division of Neonatology was recently ranked Number 1 in the US for 3 years.

8. I established the NICU in 1974 and the SIDS program in 1978 and am considered one of the top Neonatologists in the U.S., and I have been recognized as such since 1976 in national publications.

9. The SIDS program which I direct at CHOP screens approximately 300 infants a year who are evaluated as being at risk for SIDS. In this regard, our center has reviewed 25,000 sleep studies in the program to date.

10. Since 1973, I have worked with Dr. Shaffer evaluating respiratory development; lung function in neonates and children; and commercial products, product safety, and other risks for infant products. We have worked with the U.S. Consumer Product Safety Commission officials on the specific physiology of infant products and possible dangers.

11. I am the co-originator of the definitive 2000 page textbook on Fetal and Neonatal Physiology (currently in the fifth edition) that is used all over the world. I have authored more than 200 publications on neonatal respiratory conditions.

12. I remain an active reviewer of manuscripts submitted to approximately 10 journals at this time. I have authored or co-authored more than 100 peer-reviewed scientific publications and over 8 books, book chapters, invited review articles and editorials, and have submitted over 100 abstracts and presentations about diagnosis of respiratory function and improvement in respiratory care. I have been a frequent lecturer and presenter nationally and internationally on

subjects related to respiration and control of breathing. Of particular relevance, I authored many publications related to respiration and respiratory control of breathing.

B. Dr. Shaffer Academic Profile.

1. I have worked in the field of engineering, developmental physiology, respiratory physiology, and prevention of injury related to suffocation/ strangulation in infants and children for over 40 years. My *curriculum vitae* is provided in **Appendix B**.

2. I currently serve in multiple capacities – Professor of Pediatrics at Thomas Jefferson Medical College and University in Philadelphia, and Professor of Physiology and Pediatrics at Temple Medical School and University in Philadelphia.

3. I am also Director of the Nemours Center for Pediatric Lung Research, the Nemours Center for Pediatric Research, and the Office of Technology Transfer at the A.I. duPont Hospital for Children in Wilmington, Delaware.

4. I received my B.S. in Mechanical Engineering from Drexel University in Philadelphia in 1968; and my MS.E. and Ph.D. in Applied Mechanics from Drexel University in 1970 and 1972. During my graduate education, I studied mechanical control systems and fluid dynamics and respiratory biomedical engineering. I completed my post-doctoral training in the Department of Physiology at the University of Pennsylvania School of Medicine in Philadelphia.

5. From 1968-1970, I worked as a Systems Engineer at General Electric's Navigation and Control Systems Laboratory in Valley Forge, Pennsylvania. During this time, I researched navigation control systems for reentry vehicles such as Sparrow Missiles and obtained my first patent on fluid control systems for reentry vehicles. This work led to my life's work and current interest in human respiratory control and ventilator control systems.

6. My post-doctoral training involved the study of the control of respiration, including synchronization of ventilator respiration with patients' breathing patterns and pulmonary function testing in infants. In 1976, I was appointed Assistant Professor of Physiology at the School of Medicine at the University of Pennsylvania School in Philadelphia. In that role, I started research in developmental respiration and human respiratory physiology. During this time, I taught medical and graduate students various aspects of respiration. I also began publishing peer-reviewed journal articles and book chapters and developed expertise in the interaction between human respiration and medical instruments assisting breathing.

7. In 1977, I was appointed Associate Professor of Physiology at Temple University School of Medicine in Philadelphia. I also was appointed Director of the Respiratory Physiology Section in the Physiology Department. I continued my research on ways to support patients with respiratory problems, including assisting patients with breathing using mechanical ventilators. In 1987, I was promoted to full professor.

8. In 2001, I became affiliated with the Alfred I. duPont Hospital for Children in Wilmington, Delaware. I became Associate Director of Nemours Biomedical Research, Director of the Center for Pediatric Lung Research, and Director of the Office of Technology Transfer. In 2004, I became Director of the Nemours Center for Pediatric Research.

9. During my career, I have served on editorial boards of *Pediatric Pulmonology, Pulmonary Researcher, Biology of the Neonate, Journal of Orthopedic Surgery & Techniques*, and *U.S. and European Journal of Pediatrics*. I remain an active reviewer of manuscripts submitted to approximately 24 journals at this time. To date, I have authored or co-authored 283 peer-reviewed scientific publications; 77 books, book chapters, invited review articles and editorials; and have submitted 581 abstracts and presentations about diagnosis of respiratory function and

improvement in respiratory care. I have been a frequent lecturer and presenter nationally and internationally on subjects related to respiration and control of breathing. Of particular relevance, I authored many publications related to respiration and respiratory control of breathing. I frequently consult with physicians on how to treat patients having respiratory problems or disorders and run pulmonary diagnostic tests on patients in the neonatal intensive care unit (NICU), pediatric intensive care unit (PICU) and in our pulmonary clinics at A.I. DuPont Hospital for Children.

10. My clinical manuscripts have been published in *Lancet*, *The New England Journal of Medicine*, the *Journal of Pediatrics*, *Pediatrics*, *Critical Care Medicine*, and other respected and peer reviewed periodicals. In addition, I have published basic science manuscripts in *Biomedical Instrumentation and Technology, Journal of Applied Physiology*, *American Journal of Physiology*, and *American Journal of Circulatory Research*.

11. In 1969, I was awarded the Inventors Fulcrum of Progress Award from General Electric for my inventive contributions to fluid-control systems while at General Electric.

12. In 2010, I was nominated for the National Medal of Technology and Innovation for my history of awarded patents, commercialization of those patents, and my impact on advancing patient respiratory care.

13. In 1994, I began consulting for a number of commercial entities related to pulmonary physiology, thermal physiology, and prevention of infant and childhood injury associated with suffocation/strangulation insults. In this regard, I have worked with the following: Mallinckrodt Medical, St Louis, MO; Ross Products Division, Columbus, Ohio; Hill-Rom/Air-Shields, Hatboro, PA; Intertek Testing, Inc., Chicago, IL; Benechill, Inc., San Diego, CA;

BattellePharma, Inc., Columbus, OH; Arizeke Pharmaceuticals, Inc., San Diego, CA.; Fisher-Price, East Aurora, NY.

14. Since 1973, I have worked with Dr. Fox evaluating respiratory development; lung function in neonates and children; and commercial products, product safety and other risks for infant products. We have worked with the U.S. Consumer Product Safety Commission officials on the specific physiology of infant products and possible dangers.

III. EXPERIENCE IN NEONATAL RESPIRATORY DEVELOPMENT, SUDDEN INFANT DEATH SYNDROME(SIDS) , RESPIRATORY FAILURE AND PRODUCT SAFETY AND DESIGN.

Respiratory Development

A. Dr. Fox: Since 1973, I have been an academic pediatrician and neonatologist with a special interest in pulmonary medicine and respiratory physiology. I have worked on the development of pulmonary function testing in neonates which has resulted in numerous publications, book chapters, books and abstracts related to respiratory physiology and pulmonary function of the newborn. These publications are more precisely described in my attached CV.

B. Dr. Shaffer: Since 1972, I have been an academic engineer and physiologist working on respiratory development in infants, as well as respiratory innovations in children and adults. These studies were based on competitive grants I was awarded since 1974 and have resulted in numerous publications (283 peer-reviewed and 7 in press/submitted), book chapters

and books (77) and abstracts (581) related to respiratory physiology and pulmonary function of the newborn. These publications are more precisely described in my attached CV.

Sudden Infant Death Syndrome (SIDS)

About 3500 infants die from Sudden Unexplained Death (SUD) or Sudden Infant Death Syndrome (SIDS) each year in the US. It is the leading cause of death among infants 1 month to 1 year of age. It remains unpredictable despite years of research. In addition, the description and nomenclature of the problem has changed over the years including the above (SUD, SIDS) and in other countries Cot Death Syndrome. Finally, when an infant has a serious life threating event and does not die, there are event descriptors such as (Apparent Life Threatening Event (ALTE); Brief Resolved Unexplained Event (BRUE), Prolonged Apnea, and "Near Miss" to mention a few. These problems are frightening and can strike without warning. Most SIDS deaths and ALTEs are associated with sleep. The infants show no signs of trauma or suffering. The diagnosis of SIDS is made after all other causes are ruled out (trauma, genetic disease, etc.) and it is important to review medical history, sleep environment, and the autopsy to determine cause of death.

1. Fortunately, long-term complications are rare for most children with infant sleep apnea BRUE. Problems are more likely for infants who need frequent resuscitation. Health problems also are more common if the infant sleep apnea is related to another severe medical condition such as the following: Acid reflux (gastroesophageal Reflux Disorder (GERD)), Anemia, Anesthesia, Drugs, Infection, Lung disease, and Metabolic disorders. As such, these above medical conditions can cause infant sleep apnea or make it worse. {American Academy of Sleep Medicine (AASM)}

2. In addition to the above factors, overheating, changes in temperature and prone or side lying position have been reported and implicated with infant sleep apnea, BRUE, ALTE, and SIDS.

3. It is noteworthy that small preterm infants are most likely to have infant sleep apnea; however, the problem sometimes does occur in larger preterm or full-term infants. In general, sleep apnea is less common in infants under the age of six months. In this regard, during the first month after birth, sleep apnea occurs in 84 percent of infants who weigh less than 2.2 pounds and the risk decreases to 25 percent for infants who weigh less than 5.5 pounds. Apnea in infants is rare in healthy full-term newborns and its presence at birth is usually a sign of another medical condition as noted above (AASM).

4. Our SIDS program, The Infant Breathing Disorders Center at CHOP, is one of the oldest and largest in the US and was established by Dr. Fox in 1978. We have evaluated approximately 25,000 sleep studies and other pulmonary function tests. We use home monitors in our screening studies that reveal abnormal patterns of breathing, oxygen de-saturation, reflux, and/or bradycardia.

5. Sudden Unexplained Death (SUD) in Arch Dis Child. 2008; authored by Cotes et al. from McGill University, outlined the outcomes of a series of unexplained deaths in infants. Cotes et al. studied 534 SUD infants of which 508 were fully investigated (sleep environment, medical history, autopsy, etc). Of these 508 infants, 396 were SIDS; 5 were unclassified and 8 were awake and died suddenly in their parents view. The other 99 subject cohort was divided into unknown disease (71) and known disease history (28).

Respiratory Failure

Drs. Fox and Shaffer Academic Collaboration

Because of the development of pulmonary function testing biomarkers and instrumentation, we have been active in identifying the utility of pulmonary function assessment in infants and children, as well as how these tests can guide therapeutic intervention in respiratory failure. In addition, we have utilized these tests to study the efficacy of therapeutic interventions drugs, respiratory support, and the introduction of new respiratory therapies such as (CPAP, high flow nasal cannula, tracheal gas insufflations, and liquid ventilation technology) for respiratory failure. In addition, we have studied the impact of infant position (supine, prone, etc.), feeding, crying, and drug impact on neonatal pulmonary function. These studies have resulted in numerous publications, book chapters, and books related to respiratory pathophysiology on respiratory failure in the newborn. In addition, the development of respiratory function testing in the newborn has led to identification of factors associated with respiratory failure, as well as treatment guidelines for treating respiratory disorders. (See CV for details)

Drs. Fox and Shaffer Collaboration on Product Safety and Design

In this regard, our collaborative research studies and publications have focused on product safety for newborns and children. It should be noted at the outset, this case is not Dr. Shaffer's introduction to the Fisher-Price Rock 'N Play ("RNP") sleeper. In January 2016, Dr. Shaffer became a grandfather to a 33 week, preterm male. After the infant was discharged from the hospital (one month in the NICU), Dr. Shaffer's son and daughter–in–law asked his opinion on the safety of car seats and a sleeper for home use after using a bassinet for 3 months. Dr. Shaffer inspected the RNP sleeper in a manner consistent with his review of many sleep environments and concluded that the RNP was safe for his grandson to sleep in -- which he did.

A. Commercial Products: We have worked with commercial companies (Hill-Rom/Air-Shields, Ohmeda) on the development of safe warmer environments for infants. In addition, we have worked on ventilator safety and design for NICU and PICU environments, as well as published guidelines for proper use and management of patients in these settings.

B. Consumer Products: In collaboration with RAM, Inc. Chicago & Intertek International, we have used our prior infant studies (infant flows, volumes & pressures) to develop several robotic infants test models. Since human infants cannot be challenged with potential suffocation and strangulation risks, our models were able to predict which consumer products (bedding, sheets, blankets) were at risk for suffocation or strangulation. This work has been presented at national and international pediatric conferences and published. Furthermore, our robotic models have been accepted by the U.S. Consumer Product Safety Commission as a valid approach to evaluate infant products (materials, toys, any potentially ingestible item, as well as any potential strangulation product (bibs, necklaces, toys, etc.).

C. Finally, we developed test models that allow us to evaluate gas exchange (CO2 retention/oxygen deprivation) relative to commonly used sleep products (bedding, sheets, blankets, cribs, crib bumper, etc.). Certain products are not permeable to gases and others cause retention of CO2 which can impair systemic physiology leading to death.

1. Fox WW, TH Shaffer, D Stool, S Milkovich, G Rider, and X Chen: A computerized, robotic model for evaluation of infant suffocation. Pediatr Res, 51;4(2):84A, 2002.

2. Fox WW, TH Shaffer, D Stool, SM Milkovich, G Rider, X Chen, RR Stevens, and SS Stool: A Robotic Model for Evaluation of Infant Strangulation. Pediatr Res 53(4):341A, 2003.

3. Fox WW, TH Shaffer, J Hotaling, K Ibarra, J Owens,and D Stool: Assessment of Conforming Material Characteristics and Risk of Asphyxiation Fatality. Pediatr Res 55(4):348A, 2004.

4. Fox WW, TH Shaffer, D Stool, S Milkovich, G Rider, and X Chen: A dynamic model of infant suffocation: Product safety results. Shock (15):83, 2001.

IV. FACTUAL CASE CHRONOLOGY

A. Goodrich Case

1. Ms. Jan Hinson is an attorney in Alpharetta, Georgia and while visiting her daughter (Courtney Goodrich) on July 25, 2014 observed an Apparent Life Threatening Event (ALTE)/ Brief Resolved Unexplained Event (BRUE) in her newborn (7 week old, 4.5 kg) grandson (Asher Goodrich) who at the time was sleeping in a borrowed Fisher-Price RNP sleeper. From the testimony of Mrs. Goodrich and Mrs. Hinson, it appears that the infant was placed in the RNP asleep following lunch and following a transfer from a car seat at around 2:15 p.m.

2. Based on that same testimony it appears the infant was placed in the RNP without the use of restraints and was covered with a receiving blanket tucked under his arms and torso. A review of the CPSC investigative report as well as the testimony of

Mrs. Hinson raises a question about whether the receiving blanket was placed under the head of Asher at the time he was placed in the RNP. (Hinson Deposition pages 76-78; 129-131). Mrs. Goodrich confirms the use of the blanket but testified and demonstrated it was up to his chest and tucked under his arms. Based on the testimony of Ms. Hinson, Asher remained asleep until the event described below.

3. When her daughter left the room about an hour later, Ms. Hinson, according to her testimony, noted that Asher was in an unusual position with his head cocked to the left and pointed down (no restraint in place). Ms. Hinson stated that Asher was observed to be limp, blue around the eyes and lips, and appeared to be dead.

4. After Ms. Hinson picked up Asher, tried to awaken him, and held him close to her, Asher started to breathe. After consult with Asher's pediatrician, Mrs. Goodrich first took Asher to Hughes Spalding in downtown Atlanta.

5. Asher was taken to the ER triage at Hughes Spalding and the admit notes taken at 1719 reveal a "well appearing, active alert" infant, a review of the systems was negative indicating that nothing abnormal was found, his physical exam was normal, his oxygen saturation was 100% indicating no cyanosis (no blueness), and his weight was 4.5 Kg, essentially 9.9 lbs. (CHOA Records pages 14, 16). Urine analysis was significant for 6-10 white blood cells. (CHOA Records page 27). In addition the lab report indicated that liver function tests were within normal range and the CO2 electrolytes were within normal range. (CHOA Records page 26). An unsuccessful lumbar puncture was attempted times 3. It was decided later that evening that Asher would be transferred to CHOA's Egleston Hospital which

occurred around 11:00 p.m.

6. A review of the CHOA ER triage (7/25/14) records confirm that Asher had an ALTE and that he has a patent foramen ovale (PFO). (CHOA Records pages 70-81). At the time Asher was examined at Egleston, his oxygen saturation was 100% indicating no cyanosis, and he appeared well and alert. In addition, it was noted that Asher had an incomplete right bundle branch block (slight right ventricular conduction delay). Again the mother and grandmother repeated their recollection of the event. In this report, they describe the RNP as a bouncy seat which it is not. In addition, the mother reports that Asher occasionally spits up with feeds but that it is not a lot and has not inhibited growth. (CHOA Records page 76).

7. The records indicated that the etiology of ALTE/BRUE was unclear. Initial results of urine white cells were concerning. The records also indicate that the reflux history, although for amounts that were not impressive, could play a role. (CHOA Records pages 80-81). CHOA developed a treatment plan which included continuous pulse oximetry, apnea consultation, cardiovascular work up and reflux precautions but did not start Zantac for GERD at this time. (CHOA Records page 81). While in the hospital, reflux precautions were ordered, and Asher's crib was inclined to 30 degrees, and it remained at 30 degrees until time of discharge. (CHOA Cert. page 145)

8. During the morning of July 26, Asher was seen by Dr. Freed, Apnea Consultant. A similar description of the ALTE/BRUE was presented to Dr. Freed, including the "bouncy seat" misnomer. Mrs. Goodrich reported some spit up with feeds, not a lot. (CHOA Records pages 81-8). As indicated by Dr. Freed, the etiology at this

time is unclear. He stated that since the child was in a bouncy seat at the time of the event, his differential diagnosis was 1) possible upper airway obstruction: 2) reflux which can be exacerbated by a bouncy seat (no indication that the RNP is a bouncy seat); and 3) a urinary tract infection or urosepsis is possible with the elevation in white cells. Dr. Freed stated that it is important to remember that statistically 40-50% of ALTE/BRUE have no clear etiology (CHOA Records page 86) (Cotes et al).

9. The discharge summary by Dr. Taasoobshirazi stated that Asher was diagnosed with apnea. The cause of the apnea is unknown. It could be related to some reflux. The caregivers should continue to follow reflux precautions including not laying him down to sleep immediately after a feed, burping frequently, and elevating the head of the bed. (CHOA Cert. page 148). The infant was discharged with an apnea monitor.

10. On 7/31/14, baby Asher was seen for the first time following the event by his pediatrician Dr. Hilton. Mom reported that he spits up at least once after each feed, but it is small amounts. Physical exam was normal. He was observed by Dr. Hilton to spit up at least 3 times and have one choking episode while lying supine in Dr. Hilton's office. Dr. Hilton's assessment was that baby Asher had an apneic episode on 7/25/14 of uncertain etiology. His diagnosis was GERD, and Asher was started on Zantac. (Hilton Records pages 227, 228)

11. On 8/4/14, baby Asher was seen at the Sibley Heart Center for the following: patent foramen ovale (PFO), ALTE, Apnea, and GERD, as prescribed by the CHOA medical team. Asher's general appearance was normal, as well as vital signs

(respiratory rate a little high) but EKG, blood pressure, pulse and oxygen saturation all normal. Only abnormal finding was a grade II/VI vibratory systolic murmur at the left sternal border, with no radiation. At this time Asher was still on the apnea monitor and was prescribed Zantac for GERD by Dr. Hilton, as testified by Mrs. Goodrich. (Sibley Records pages 9-12)

12. As ordered, monitor downloads were provided to the Apnea Clinic, after 12 out of 12 days (8/8/14) there were no patient waveform downloads; and after 21 out of 21 days there was 1 patient waveform download that was due to the loose apnea belt or the child was breathing shallow. Dr. Freed's impression was that the studies were normal.

13. On 8/27/14, Asher was seen for the first time in the Apnea Clinic by Dr. Freed. Mom reported that Asher had a single episode of gagging and 2 episodes of choking. She reported he spits up frequently. His impression was reflux. (CHOA Cert. pages 186-188). In a 8/27/14 letter to Dr. Hilton, Dr. Freed noted that the gagging/choking episodes "sound like classic reflux events." (CHOA Cert. page 201). The monitor downloads continued up to 1/12/15 and his impression was no abnormal waveforms detected; however, monitor usage was dismal.

14. Later follow-up medical visits were for persistent ear infections, well baby visits, and conductive hearing loss which resolved after tube placement. On 10/8/15, Asher had a well-baby visit with Dr. Hilton.

15. The most recent visit with Dr. Hilton we have reviewed was 7/27/17. It was a 3 year well visit. Like all intervening visits, with the exception of normal childhood

sick visits, this was a normal checkup with no abnormal findings other than an insignificant skin rash. (Hilton Records pages 186-189).

V. OPINION ON FISHER –PRICE "ROCK'N PLAY SLEEPER" DESIGN AND MEDICAL CAUSATION WITH RESPECT TO ASHER GOODRICH

The following opinions on the above sleep products are based on our collective training, education and experience in engineering, respiratory physiology, medicine, and extensive experience working on the prevention of injury and promotion of safety in both commercial and consumer products for infants and children.

1. Based on our work with Intertek International, the mattress materials in the product do not pose a risk with respect to CO2 re-breathing based on the non-porous nature of the material. Non-porous materials do not absorb CO2 and therefore do not promote re-breathing.
2. The mesh on the sides of the sleep product eliminates the risk of CO2 re-breathing. Since there is free convection of air through the mesh, this airflow can disperse CO2 from the infant's airway passages.
3. The 30 degree inclined sleeping angle of the RNP does not increase the risk of airway/respiration compromise or of SIDS or ALTE/BRUE events and is consistent with acceptable medical practice.
4. The product's narrow base and restraint, as well as the small elevation under the infant's legs, prevents the baby from sliding and/or turning in the sleeper, thus reducing the risk that respiration could be compromised. In addition, the restraint, if properly used, further maintains the infant's positioning.

5. The legs of the sleeper are well constructed and with the restraint, there is little risk that the infant could fall from or within the sleeper.

6. The hard shell back in the sleeper provides firm alignment of the head and torso, so that there is no flexion of the neck/airway while the infant is resting on a 30 degree incline.

7. Based on the biomechanics of an infant's head & torso resting on an incline <35 degrees, as well as the weight distribution (head and torso); the head will remain at rest and the balance of forces are such that the head will not fall towards the chest/torso (see Appendix C). In a car seat quality control (QC) study (unpublished), Dr. Fox studied a small series of term infants in car seats in which the incline of the car seat was gradually increased from 20 to 60 degrees above the horizontal (measured with an inclinometer) while the infants were restrained and resting comfortably. It was noted that none of the infants flexed their head forward until the incline was greater than 50 degrees, thus supporting the biomechanical analysis above. Finally, the study by Rieterer *et al.* on "Influence of head–neck posture on airflow and pulmonary mechanics in preterm infants, Pediatric Pulmonology, 17:149-154, 1994, report clinical data that also support that < 30 degree incline does not impair airflow or lung function in even preterm infants.

8. We decided to perform a conformational study on 6 infants (age, size and weight of Asher) in the RNP. The consented parents, while supervising the study, were asked to place their infants in the RNP, after measurements (overall length, length from rump to shoulder, length from shoulder to crown, dimensions related to position in the RNP, head circumference and weight) and placement of the

Massimo Pulse Ox. The infants were videoed for up to 45 min. in the RNP with and without the restraint in place. Also, without the restraint, mothers placed their infants at the edge of the hard shall. At no time during the videoing did the pulse OX read below 95% saturation and in most cases was 97-100%. It is noteworthy that because of the shape of the plastic insert, the infants, even without the restraint system buckled, were restrained in place by the shape of the plastic and while the infants' heads turned left and right, the infants' torsos remained firmly in place unless manipulated by an adult. There was no suggestion from our observation of the infants that such positioning could induce respiratory risk. It is also noteworthy that the restraint system, when utilized with these infants, remained below the infants' sternum, so there was no respiratory risk associated with the restraint in infants of this size.

9. Although the AAP guidelines suggest placing infants "wholly on their back," we believe the guideline is intended to instruct parents to ensure that infants are placed on their backs while sleeping, not on their side or prone. We must emphasize that the "Guidelines" were presented by a relatively small committee (4 pediatricians) and are not absolute, but are intended to inform general pediatricians and parents about safe sleep environments. The perceived risk addressed in the Guidelines, e.g., in inclined sleeping, an infant might slide to the bottom of the crib into a position that might compromise respiration is a perceived risk not found in the RNP. First, a RNP is not a crib, and second, because of the design characteristics of the RNP, and infant is not able to slide to the bottom into a position that might

compromise respiration. This latter opinion is directly supported by our observations of infants in hospital settings as well as in the RNP.

10. In the CHOP NICU, the largest in the world for respiratory care, infants are regularly placed on their backs on inclines up to 30 degrees. Currently, in our hospital systems, close to 100% infants (including preterm infants) are placed on an incline of approximately 10 to 30 degrees above the horizontal in the supine position. These infants are supervised and monitored 24/7 for months and there have been no adverse events associated with this practice. We note that CHOA ordered reflux precautions for Asher, inclined his crib throughout his hospital stay to 30 degrees, and upon discharge, he was ordered to elevate his crib which his parents did for almost a year.

11. Based on a number of published physiological and medical studies there are significant positional advantages with respect to improved lung volume, lung mechanics, gas exchange and longitudinal tension in the airway (preventing airway collapse) when a supine infant is placed on an incline. Finally, many health care providers use the 30 degree incline position as ordered at CHOA to prevent reflux.

12. Based on our studies, clinical practice and experience, we do not see a basis for a respiratory risk associated with supine infants placed on a small incline versus a no incline, horizontal surface.

13. Even in the safest sleep environment (Hospital Sleep Laboratory, NICU & PICU), infants and children have apnea events. As such, infants can have prolonged pauses in breathing that last 20 seconds or longer. Typically, these patterns have repeated pauses in breathing that last less than 20 seconds and are associated with related

problems such as low oxygen or a slow heartbeat. In serious cases, infants may require resuscitation or other urgent care.

14. During hospital sleep studies, infants often have several obstructive apnea events (OAE) and central hypoxic events at night (the differential diagnosis is only possible in a sleep laboratory). Underlying problems (noted above) which lead to these events are precipitated by viral and/or bacterial infections, acid reflux (GERD), bronchopneumonia, airway reactivity, obesity, floppy airways due to chronic lung disease and central depression of respiratory control.

15. Based upon our review and analysis of the Rock 'N Play sleeper and its design characteristics, based upon our review of all of the medical records in this case as well as the testimony of witnesses in this case, and based on our training, education, and experience, it is our collective opinion that the Rock 'N Play sleeper provides a safe sleep environment for infants when used according to the instructions of the manufacturer. Furthermore, and notwithstanding the fact that the restraints were not in use at the time of the apneic event experienced by Asher, it is our opinion that the Rock 'N Play sleeper did not play a medically causative role in the event of April 25, 2014. Rather the event was more likely than not caused by a factor described in the following paragraph.

16. Regarding the Goodrich medical reports, although there were several underlying medical issues noted; there is insufficient information to establish the exact cause of the ALTE/BRUE or the length of the event. However, based on the chronology of the medical events, it appears that the most likely cause was gastroesophageal reflux. This is supported by the testimony of Mrs. Goodrich who reported that

Asher spit-up after feeds. It is also supported by the fact that before he was placed on reflux medication by his pediatrician Dr. Hilton, on at least one occasion -- and this occasion was in the office of Dr. Hilton four days after discharge from CHOA -- Asher spit up at least 3 times and had one choking episode while lying supine in the doctor's office. Also, Dr. Freed's records reflect that following discharge from CHOA, Asher experienced a single episode of gagging and two episodes of choking and he considered this classic reflux. After Asher Goodrich was treated for GERD with medication and elevated sleep environment, there were no more apnea events and/or reflux problems, suggesting that GERD and microaspiration of acid reflux likely initiated the Infant Sleep Apnea/ALTE/BRUE observed by Ms. Hinson. In addition, Asher Goodrich is now a thriving infant with no notable medical problems. Finally, as noted above (SIDS section), fortunately long-term complications are rare for most children with infant sleep apnea BRUE. Problems are more likely for infants who need frequent resuscitation and have health problems related to another severe medical condition.

In addition to the material provided in our report, we are attaching the following information:

- Appendix D: Statement of Compensation
- Appendix E: Materials Read and Reviewed
- Appendix F: Deposition Testimony and Trial Testimony Provided Over the Last Four Years

As further investigation or new information becomes available, we reserve the right to revise and supplement this report.

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